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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,997	07/26/2001	Donald W. Petersen	06317-038002	1532

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EXAMINER	
WITZ, JEAN C	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/915,997	PETERSEN ET AL.	
	Examiner	Art Unit	
	Jean C. Witz	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-71* is/are pending in the application.

4a) Of the above claim(s) *69-71* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 43-71 have been considered but are moot in view of the new ground(s) of rejection.

Election/Restrictions

Newly submitted claims 69-71 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The invention recited in claims 69-71 and the invention recited in claims 43-68 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, a patient having a bone defect can be treated with a materially different product such as bone marrow composition.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 69-71 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 43-60 and 62-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sander et al. (5,356,629) combined with Hanker et al. (4,619,655).

Sander et al. teach compositions for effecting bone repair that biocompatible particles dispersed in a matrix. The disclosed compositions have the benefit of effecting bone repair while possessing improved moldability, workability and other handling characteristics upon being wetted with appropriate liquid medium. The matrix components disclosed by Sander et al. include cellulose ethers such as recited in claim 4 (see col. 2, lines 57-66). The matrix component may also be hyaluronic acid (as recited in claim 7 – see col. 2, lines 67-68). Sander et al. teach that the biocompatible

particles may be bioresorbable or nonbioresorbable. While Sander et al. acknowledge in the Background of the Invention that plaster of paris (calcium sulfate hemihydrate) is known as a bioresorbable substance is conventionally used as a bone graft material, Sander et al. do not explicitly list calcium sulfate hemihydrate as a bioresorbable particle in the body of the patent specification.

Hanker et al. support the statements of Sander et al. that calcium sulfate hemihydrate is used as a resorbable bone implant. It is mixed with water and is applied to the damage or defect in the bone. The calcium sulfate hemihydrate, upon hydration, hardens in the area of implantation and acts both as a source of calcium for bone growth in the area of the implant, acts as a support for the damaged area during the time of repair, and stimulates revascularization and bone formation.

It would have been well within the skill and obvious to one of ordinary skill in the art at the time the invention was made to select calcium sulfate hemihydrate as the bioresorbable particle to be used in the formulation of the composition of Sander et al. Sander et al. provides a non-limiting list (the teaching of a U.S. patent is not limited to its recitations of preferred embodiments) and provides no proscription against its use. Insofar as the statements found at column 1, lines 30-34 of the Sander et al. patent are asserted be a teaching away from the use of calcium sulfate hemihydrate, it is clear from the teaching of Hanker et al. at col. that resorbability of a calcium sulfate hemihydrate may be adjusted by adjusting the density of the calcium sulfate hemihydrate to obtain any desired resorption rate. Further, it is exactly the teaching of Sander et al. that motivates the addition of a matrix such as claimed to a calcium sulfate

hemihydrate bone graft composition to improve the workability. Finally, with regard to the specific amounts of each component, Sander et al. teach that the bioresorbable component is present in the unwetted state from about 64 – 94% and that the matrix is present in the composition in the unwetted state from about 6 – 36% of the composition. After being wetted, the composition preferably comprises 35 – 75% bioresorbable component and the matrix preferably comprises 5 – 20% of the composition. Since the physical properties of both the calcium sulfate and the plasticizing (matrix) substances are well known and since the references teach that determining the desired time and degree of workability for the specific bone defect or damage is well within the skill of the practitioner, it would have equally been well within the skill of the practitioner at the time the invention was made to engage in a reasonable and not undue amount of experimentation to determine a desired recipe for a bone graft composition containing calcium sulfate, a plasticizing substance as disclosed and the amount of wetting solution required, particularly since the amounts claimed are either well within the ranges disclosed or extremely close, as in the case of the ranges taught for the matrix component. It is also noted that the patent uses the term "about" which indicates that there is at least some leeway in the amounts taught to be effective.

With regard to claim 60, the claim recites a bone graft substitute composition consisting essentially of calcium sulfate, a mixing solution and a plasticizing substance. The transitional phrase "consisting essentially of" is deemed to limit the scope of a claim to the specified components in the claims but also allows inclusion of "those [components] that do not materially affect the basic and novel characteristic(s)" of the

claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). In this case, the prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." If Applicants contend that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989). In this case, the instant specification teaches that other ingredients may be included with the claimed composition including demineralized bone matrix, bone morphogenic proteins and any number of other ingredients such as listed at page 4 of the specification.

Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hanker et al. (4,619,655) combined with GB 999,487 in view of Yim et al.

Claim 61 recites closed transitional phrasing to limit the composition to the calcium sulfate hemihydrate, the plasticizing substance and the mixing solution. Of these three ingredients, Hanker teaches two - the calcium sulfate hemihydrate and the mixing solution - that are successfully used by themselves as a bone graft. Hanker teaches that calcium sulfate hemihydrate is a conventional medical material (used to make casts) that can now be used as a bone implant. It is mixed with water and is applied to the damage or defect in the bone. The calcium sulfate hemihydrate, upon hydration, hardens in the area of implantation and acts both as a source of calcium for bone growth in the area of the implant, acts as a support for the damaged area during the time of repair, and stimulates revascularization and bone formation.

GB 999,487 teaches that an addition of a cellulose ether to calcium sulfate hemihydrate acts as a set retardant. As a result, it is clear in the state of the art that the both the set time and the consistency, i.e. workability, of calcium sulfate hemihydrate can be adjusted by the addition of a plasticizing agent in specific situations where such a workability are required. One of ordinary skill in the art would have been motivated to improve the workability of the composition of Hanker by the addition of the plasticizing substance GB 999,487 because each of the components in the claims are clearly disclosed and well known for their individual contribution to the activity of the composition. Since Yim et al. includes the same plasticizing/set retardant substances along with calcium sulfate hemihydrate in a bone graft composition, one of ordinary skill

in the art would be aware that these set retardant components would be appropriate for surgical use.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jean C. Witz
Primary Examiner
Art Unit 1651